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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/276,455 03/25/99 FERSHT

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EXAMINER

FIELDS, I

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/25/01

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/276,455

Applicant(s)

FERSHT ET AL.

Examiner

Iesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,9-21, and 29-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Applicant's amendment received July 10, 2001 (Paper No. 19) has been received and entered. Claims 1 and 8 were amended, consequently claims 1-50 are pending in the instant application and claims 1, 9-21 and 29-31 are under examination.

Response to Amendment

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claim 1 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is **maintained**.

Applicant's have asserted that the terms used in claim 1 are described in the specification.

Applicant's arguments have been fully and carefully considered and they are not deemed to be persuasive.

Claim 1 recites a chaperon polypeptide of a GroEL sequence shown in Figure 7, or a corresponding sequence of a substantially homologous chaperon polypeptide, or a modified, mutated or variant sequence thereof having chaperon activity.

As stated previously, the specification and the claim do not indicate which distinguishing attributes are shared by the members of the genus. The scope of the claim as written includes modifications, mutations, variants and/or any sequence which is "substantially homologous" to the claimed polypeptide. While the Examiner has noted the listing of the hsp60 class of chaperon proteins in the application, the amino acid sequence shown in Figure 7 nor the specification is sufficient to describe the claimed invention.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

2. Claims 1, 9-11, 14-21, and 29-31 are under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **maintained**.

A topographical error was made on page 5 of the Office Action which states that Claim 8 is rejected under 35 U.S.C. 112, second paragraph. As clearly stated on

PTO Form 326 and on pages 2 and 3 of the same Office Action, Claim 8 was withdrawn from consideration. Therefore, non-elected claim 8 was not examined and will not be further addressed.

Regarding claims 1, 9-11, 14-21, and 29-31, as stated previously, the claims are vague and indefinite in the recitation of a "substantially homologous" chaperone polypeptide and a "modified, mutated or variant" sequence thereof. One of skill in the art would be unable to determine the metes and bounds of such limitations. Without a clear definition as to what constitutes "substantially homologous" and exactly which variants, modifications, and mutations are encompassed by the claimed invention, one of skill in the art would be unable to replicate the claim.

Claim Rejections - 35 USC § 102

3. Claims 1 and 9-17 rejected under 35 U.S.C. 102(b) as being anticipated by Braig et al. is **maintained**.

Applicant's have asserted that the invention is directed to chaperone polypeptides that are active in the folding and maintenance of structural integrity of other proteins. Applicant's have further asserted that Braig et al. does not teach of fragments of GroEL.

Applicant's arguments have been fully and carefully considered and they are not deemed to be persuasive.

As stated previously, Braig et al. disclose the entire amino acid sequence of *E. coli* GroEL (including fragments). Because the polypeptide sequences are inherent to the entire amino acid sequence of *E. coli* GroEL disclosed by Braig et al. the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

4. Claims 1, 18-21 and 29-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Braig et al. in view of Holland et al. is **maintained**. This rejection is further applied to claims 9-17.

Applicant's have asserted that Braig et al. does not teach of "fragments of GroEL" that have chaperone activity. Applicant's have further asserted that one of skill in the art would not be motivated to make a recombinant *E. coli* GroEL fusion polypeptide.

Applicant's arguments have been fully and carefully considered and they are not deemed to be persuasive.

The claims are drawn to GroEL polypeptides.

Braig et al. disclose the entire amino acid sequence of *E. coli* GroEL. Braig et al. further teach that chaperons are large multisubunit assemblies essential in mediating ATP-dependent polypeptide chain folding.

Braig et al. does not teach of a recombinant *E. coli* GroEL fusion polypeptide.

Holland et al. teach of a process of making recombinant fusion polypeptides including polypeptides of bacterial origin (See Summary of the Invention).

Given that 1) Braig et al. has taught of the entire amino acid sequence of *E. coli* GroEL and that 2) Holland et al. has taught of a process of making a recombinant fusion polypeptide it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to identify fragments of GroEL that have chaperone activity and further use the polypeptide as a diagnostic tool in the treatment of disease. One would have been motivated to identify such polypeptides in view of the teachings of Holland et al. that such polypeptides may be useful in diagnostic assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

September 24, 2001



MARK NAVARRO
PRIMARY EXAMINER